REMARKS

Claims 1-9 were pending, claims 10-13 were previously cancelled, claims 14 and 15 are new. So claims 1-9 and 14-15 are now pending.

Rejections under the first paragraph of 35 USC § 112

Claims 1 – 9 were rejected for introduction of new matter in the prior claim amendment to claim1, based on alleged absence of basis in the specification for the open ended claim that "the water soluble flavoring is present at a concentration greater than 0.2%". Claim 1 has been amended to now read "the water soluble flavoring is present in the range between about 0.1% and about 1.5%. Claim 3 has been amended to now read "the water soluble flavoring is present in the range between about 0.2% and about 1.5%. The example embodiments enumerated in the specification are 1% in a capsule containing 35% water, *which corresponds to 1.4% of a shell dried to 6% water* (see page 3, lines 11-13), 0.5 % or more in a gelswatch containing 35% water, *which corresponds to 0.7% or more in a dried capsule containing 6%(* see page 5 lines 23-25), and that 0.25 – 0.5 is the preferred soluble flavoring for a fish oil composition with 80% Omega-3 Fatty Acids (see bottom of page 6 to top of page 7). Given the range, illustrated by embodiments in the specification, to wit about 0.25% to about 1.4%, and the noted variability due to Omega-3 purity, the claims as amended claiming about 0.1% to about 1.5% in Claim 1, and alternatively about 0.2 to about 1.5 in Claim 3, are certainly justified.

The Applicant, therefore, respectfully requests withdrawal of the 35 USC §112 rejections.

Objective Evidence

Introduction of an Additional Declaration under 37 CFR 1.132

Applicant hereby introduces Exhibit 1, an additional Declaration under 37 CFR 1.132 from Dr.Oliver B. Cooperman, M.D. of Rimrock Foundation in Billings, Montana who is frequently in a position to prescribe Nordic Naturals ®ProEPA and ProOmega to his

patients in his medical practice. In the declaration, he attests that these products satisfy a long felt need recognized by physicians for palatable fish oil formulations which achieve patient compliance to take the formulations as prescribed. Both of these formulations contained 1% lemon flavoring in the shells. Dr Cooperman attributes the improvement to be largely attributable to the flavoring in the shells.

Summary of Previously Submitted Objective Evidence

Applicant respectfully requests reconsideration of previously submitted Objective Evidence in light of the amendment to Claims 1 and 3, and to additional arguments herein set forth.

Applicant submitted a **Declaration showing unexpected results on 4/10/2006**, which was said in the OA to be unpersuasive because "the scope of the claims was broad covering all flavors in any amounts greater than 0.2%, while the declaration was limited only to one flavor Firmenich #52311A at a specific concentration of 0.5 to 1.0%". Indeed at the bottom lines of page 7 of the declaration, the declarant states "that suitable flavoring occurred within a surprisingly narrow range of concentrations between about 0.25 and 1.5% flavoring". **This now corresponds almost exactly to the scope of the amended claims.** While the declarant only gave detailed sample lab data for one flavoring, he declared that similar results were obtained from testing at least ten different natural flavorings, including strawberry, peppermint, lemon, peach, orange and plum (see top of page 8). Also declarant states in his summary that "the flavor content for a palatable capsule was between 0.25 and 1.25% for a wide variety of natural flavors". The Applicant submits that if there was a perceived discrepancy between the claimed invention and the declaration, it certainly does not exist for the amended claims.

Applicant also submitted a **Declaration Showing Commercial Success** on 9/25/2006. In that declaration he indicated that Flavored Gel Caps made by Nordic Naturals, Inc. all in accordance with the **claimed** invention, and having approximately 1% flavoring in gelatin shells, had captured approximately 43% of the United States market for fish oil capsules sold in Health Food Stores in July 2006, certainly evidence of commercial success by any standard. The OA states, "Regarding commercial success, it does not overcome the obviousness rejection. The claims encompass the flavored gelatin capsules disclosed by Lachman, because the claims encompass the flavoring agent disclosed by Lachman." Applicant respectfully traverses the examiner's statement that "the claims encompass the flavoring agent disclosed by Lachman". The claims, as amended, encompass "water soluble flavoring present in the range between about 0.1% (or alternatively 0.2% for claim 3) and about 1.5%". Lachman discloses "flavorings such as ethyl vanillin (0.1%) and essential oils (not exceeding 2%) to impart desirable odors to capsules and for taste purposes for chewable capsules. Ethyl vanillin is a synthetic chemical which is 3.5 times stronger than natural vanilla but has a somewhat different flavor. It is a yellowish white solid, which is INSOLUBLE in water. Natural vanilla is a complex mix of many compounds, such as vanillin and related esters. "Essential oils" is not really enabled by Lachman's disclosure; however it is assumed that like other oils they are likewise INSOLUBLE in water. Wikipedia defines essential oils as "any concentrated, **hydrophobic** liquid containing volatile aroma compounds from plants". It states that they are also known as **volatile** or **ethereal** oils, or simply as the "oil of" the plant material from which they were extracted, such as *oil of clove*. The term **essential** indicates that the oil carries distinctive scent (essence) of the plant. The claims all call for **water soluble**

flavorings and thus are mutually exclusive of Lachman's water insoluble flavorings. The water solubility is important for obtaining an even distribution of the flavoring in the gelswatch from which the capsules are made, whose major ingredient is water. Also, the new claims 14 and 15 identify the flavorings which are referred to in Claim 1 and Claim 3, and they are not encompassed by Lachman at all.

Rejections under 35 USC § 103

Claims 1-9 were rejected as being unpatentable over Lachman in view of US Patent 5,955,102 ('102). Claim limitation '1d' claims a water soluble flavoring. present in the range between about 0.1% and about 1.5% and water present in the range of about 6% to about 10%. Neither Lachman nor '102 disclose either of these limitations. The water requirement is within the range often used in formulating gelatin capsules, though a wide range of compositions can be used, and it would not have been obvious to one of ordinary skill in the art at the time of the invention that this composition was required for flavored fish oil capsules. It would also not have been obvious to one of ordinary skill in the art to use water soluble flavorings given Lachman's disclosure of insoluble flavorings.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 1d has claim limitations of **water soluble** flavoring present in the range between about 0.1% and about 1.5% and water in the range of 6% to 10%. These claim limitations are not found in the prior art either alone or in combination. Similarly,

Claim 3 calls for water soluble flavoring in the range between about 0.2% and 1.5, which are also not found in the prior art.

Applicant respectfully requests allowance of Claims 1-9 and 14-15, and timely issuance of a Notice of Allowance.

Applicant further respectfully asserts that under Graham vs. John Deere Co. a comparison of the subject matter sought to be patented and the prior art reveals that the patent as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art. There is not a single enabling disclosure in all the time that modern gelatin capsules have been in use since invented by R.P Scherer in 1933 of gelatin capsules flavored with water soluble flavoring prior to the invention date.

It is also respectfully submitted that the objective or secondary considerations are both relevant and probative under Graham v. John Deere, proving unexpected results, commercial success and long felt need.

For all of these reasons Applicant respectfully requests allowance of all outstanding claims and timely issuance of a Notice of Allowance.

Respectfully Submitted,

/Howard E. Lebowitz/

Foothill Law Group, LLP
Howard E. Lebowitz
Registration Number 44,864
Attorney of Record
19682 Hesperian Blvd., Suite 208
Hayward, CA 94541
510-785-8070